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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,125	05/31/2001	Michael W. Pariza	960296.97958	2562

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EXAMINER
STILLER, KARL J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/871,125	Applicant(s) PARIZA ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1 (in part insofar as control of body fat is achieved by the administration of a lipoxygenase inhibitor), and Claims 2-9, drawn to a method of controlling body fat in an animal, comprising the administration of an amount of a lipoxygenase inhibitor sufficient to control body fat in the animal, diversely classified in Class 514, for example, Subclasses 311, 420, 460, 736, 739, etc.

II. Claim 1 (in part insofar as the control of body fat is achieved by the administration of conjugated linoleic acid) and Claims 10-19, drawn to a method of controlling body fat in an animal, comprising the administration of an amount of conjugated linoleic acid sufficient to control body fat in the animal, classified in Class 514, Subclass 739.

III. Claim 20 (insofar as the inhibition of heparin-releasable lipoprotein lipase activity is accomplished by treating a cell with a lipoxygenase inhibitor), and Claims 21-30, drawn to a method of inhibiting heparin-releasable lipoprotein lipase activity associated with a cell, comprising treating the cell with a lipoxygenase inhibitor, diversely classified in Class 514, for example, Subclasses 311, 420, 460, 736, 739, etc.

IV. Claim 20 (insofar as the inhibition of heparin-releasable lipoprotein lipase activity is accomplished by treating a cell with an antisense oligonucleotide of lipoxygenase mRNA), and Claims 31-33, drawn to a method of inhibiting extracellular activity associated with a cell, comprising treating the cell with an antisense oligonucleotide of lipoxygenase mRNA, classified in Class 536, Subclass 24.5.

V. Claim 34 (in part insofar as the reduction of triacylglyceride levels in a cell is accomplished by treating the cell with a lipoxygenase inhibitor), and Claims 35-44, drawn to a method of reducing triacylglyceride levels in a cell, comprising contacting the cell with an amount of a lipoxygenase inhibitor sufficient to reduce triacylglyceride levels in the cell, diversely classified in Class 514, for example, Subclasses 311, 420, 460, 736, 739, etc.

VI. Claim 34 (in part insofar as the reduction of triacylglyceride levels in a cell is accomplished by treating the cell with an antisense oligonucleotide of lipoxygenase mRNA), and Claims 45-47, drawn to a method of reducing triacylglyceride levels in a cell, comprising contacting the cell with an amount of an antisense oligonucleotide of lipoxygenase mRNA sufficient to reduce triacylglyceride levels in the cell, classified in Class 536, Subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and III-IV and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The inventions of Groups I-II are methods which function to control body fat in an animal, whereas the inventions of Groups III-IV are methods which function to inhibit heparin-releasable lipoprotein lipase activity in a cell, and whereas the inventions of Groups V-VI are methods which function to reduce triacylglyceride levels in a cell.

Inventions I and II; III and IV; V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The invention of Group I is a method which operates by the administration of a lipoxygenase inhibitor, whereas the invention of Group Ii is a method which operates by the administration of conjugated linoleic acid. The invention of Group III is a method which operates by treating a cell with a lipoxygenase inhibitor, whereas the invention of Group IV is a method which operates by treating a cell with an antisense oligonucleotide of lipoxygenase mRNA. The invention of Group V is a method which operates by treating a cell with a lipoxygenase inhibitor, whereas the invention of Group VI is a method which operates by treating a cell with an antisense oligonucleotide of lipoxygenase mRNA.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

If the invention of Group I, III, or V is elected, applicants are further required to make the following species election:

Claims 1-9; 20-30; 34-44 are generic to a plurality of disclosed patentably distinct species comprising lipoxygenase inhibitors. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, which is a single disclosed lipoxygenase inhibitor, even though this requirement is traversed.

The search for all lipoxygenase inhibitor species useful in the method herein presents an undue burden on the office due to their dissimilar structural nature and correspondingly diverse classification. For example, a-pentyl-3-(2-quinolinylmethoxy)-benzenemethanol is classified in Class 514, Subclass, 311; indomethacin is classified in Class 514, Subclass 420; 5-HETE lactone is classified in Class 514, Subclass 460, nordihydroguaiaretic acid is classified in Class 514, Subclass 736; eicosatriynoic acid is classified in Class 514, Subclass 739.

Please also note that the search is not limited to the patent files.

Claims 1 and 10-19 are generic to a plurality of disclosed patentably distinct species comprising mammals, avians, and fish. Applicant is required under 35

U.S.C. 121 to elect a single disclosed species, which is a single disclosed mammal species, avian species, or fish species, even though this requirement is traversed.

The search for all species of animals acted upon by the methods herein presents an undue burden on the office due to their dissimilar biological (e.g., structural, enzymatic, etc.) systems and their correspondingly diverse treatment within the art. It is a well-settled fact that metabolism of actives are often not predictable. It is well known that enzyme systems to metabolize actives differ between animal species, and that efficacy or toxicity often cannot be accurately predicted for one species, given the administration of the compound to another.

Therefore, due to the structural diversity of active compounds useful in the methods herein and their corresponding diverse classification, and the dissimilarities among species acted upon by the methods herein, the search for all species of all lipoxygenase inhibitor species useful herein or all species of animals acted upon in the methods herein would present an undue burden on the office.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the

examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction and specie election is considered complex, a call to the attorney for a telephonic election was not made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
December 20, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600